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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/737,144	12/15/2003	Su Il Yum	DURE-050	6360

31498 7590 06/30/2008

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
06/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/737,144	YUM ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-8,10-50 and 52-79* is/are pending in the application.

4a) Of the above claim(s) *32-40,52,53,56 and 65-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-8,10-31,41-50,54,55,57-64 and 68-79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges receipt of request for extension of time, amendment and remarks filed 3/17/08. Claims 5, 7, 12 and 57 are amended. Claims 1, 2, 4-8, 10-50 and 52-79 are pending.

Claims 54-56:

Applicant reinstates claims 54-56 because claims 54-56 were improperly withdrawn from consideration. Claims 54 and 55 recite that the solvent is an organic acid derivative (54) and the solvent is an organic acid ester (55). Since ethyl lactate is an organic acid derivative and ester of organic acid, ethyl lactate meets the limitation of claims 54 and 55 and were inadvertently withdrawn with claims 52, 53 and 56. For claim 56, the claim states that the solvent comprises an alcohol and an organic acid residue. While ethyl lactate is formed form lactic acid and ethanol, a solvent that comprises an alcohol and organic acid residue is not ethyl lactate. Applicant has not also indicated that the ethyl lactate is an alcohol and organic acid residue. If applicant says on the record that the ethyl lactate solvent comprises an alcohol and an organic acid residue, then ethyl lactate will meet the claim. Claim 56 states that the solvent comprises an alcohol and an organic acid residue and because applicant has not specifically stated that ethyl lactate is meets the limitation of claim 56, claim 56 is withdrawn. Using the specification as a guide, at paragraph [0040], ethyl lactate is defined as a compound possessing an alcohol and an organic acid residue. If the claim had stated that the solvent is a compound

possessing an alcohol and an organic acid residue, then claim 56 would properly read on ethyl lactate, the elected solvent.

Applicant is respectfully requested to advise the examiner on the issue of the relationship of ethyl lactate and a solvent comprising alcohol and organic acid residue.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 4-6, 10-13, 17, 18, 23-30, 46-50, 54, 55, 57, 70, 71 and 76-78 remain rejected under 35 U.S.C. 102(b) as being anticipated by Tipton et al. (US 5,747,058) for reasons of record and reiterated herein.

Tipton discloses a composition comprising HVLCM, and with sucrose acetate isobutyrate specifically employed (abstracts, column 2, lines 43, 46, 55, 60-65; column 4, lines 2-67; column 5, lines 1-33; column 8, lines 51-67; column 12, lines 46-50) meeting the recitation of HVLCM in the claims; the composition contains surfactants (column 11, lines 40-67; column 12, lines 1-17) in amounts of 0.5-30% and having 1-5% preferred that meets network former of the claims

and specifically claims 26-29, oily components (column 12, lines 18-45) in amounts of 0.5-50% and with 1-10 preferred meeting the rheology modifier of the claims and specifically claims 23-25, water or DMSO or ethyl lactate or triacetin (column 2, lines 49 and 50; column 12, line 51) meeting the solvent requirements of the claims, additives such as preservative, antioxidants, stabilizers, vitamins (column 12, line 65 to column 13 line 4) meeting claims 17 and 18, and drugs such as codeine (column 7, line 62) meeting claims 29, 30, 70, 71; the formulation of Tipton is placed in gelatin capsules for oral administration (claim 88) meeting claims 13 and 14. Claims 46-50 recite the properties of the composition and the composition of Tipton would inherently possess these properties. The composition of Tipton would inherently possess the characteristics of the composition recited in claims 2 and 4.

Response to Arguments

3. Applicant's arguments filed 03/17/08 have been fully considered but they are not persuasive.

Applicant argues that Tipton does not anticipate the claims because there is no single particular composition in Tipton that contains HVLCM, solvent, rheology modifier and a network former because Tipton generally discloses pharmaceutical compositions that include HVLCM component, that may include one or more of a large list of active agents, optionally any number of a large list of biodegradable and non biodegradable polymers, any number of vast list of oils and fats, any material found in a vast list of carbohydrates and carbohydrate derivative, any number of materials found in an extensive list of surfactants and co-surfactants, and any number of solvents and preservatives, stabilizers, antioxidants, coloring agents, flavoring agents, humectants, sequesterants, vitamins and vitamin precursors.

The examiner disagrees that Tipton does not teach a composition comprising a drug, HVLCM, network former, rheology modifier and a solvent as claimed in claim 1. Applicant's narration in the remarks of the composition of Tipton supports the anticipation of the claims designated in the rejections above under 35 USC 102. For example claim 1 is a generic composition that comprises a drug, high viscosity carrier material, network former, rheology modifier and a solvent. Thus applicant's characterization of the composition of Tipton as containing HVLCM component, one or more of a large list of active agents, optionally any number of a large list of biodegradable and non biodegradable polymers, any number of vast list of oils and fats, any material found in a vast list of carbohydrates and carbohydrate derivative, any number of materials found in an extensive list of surfactants and co-surfactants, and any number of solvents and preservatives, stabilizers, antioxidants, coloring agents, flavoring agents, humectants, sequesterants, vitamins and vitamin precursors represents further support that Tipton teaches the claimed composition. The comprising language of the composition is open; drug in claim 1 is broad and can be any drug, rheology modifier can be any of those on the list applicant refers to; solvent and network former is any of the solvents and any of the network formers listed by Tipton and referred to by applicant in the remarks. Applicant admits of the composition of Tipton as being suitable for oral administration when applicant says the composition of Tipton is provided in the form of a mouth wash and for topical oral administration; also claims 88 and 89 of Tipton specifically recite the composition as formulated as a capsule, which is for oral administration. Applicant's reference to column 9, line 61 of Tipton is noted and shows that the list of carbohydrates consists of sugars such as fructose and dextrose, sucrose, maltose, cellobiose and lactose and polysaccharides and this list is not exhaustive. Tipton lists solvents

that are known common solvents used in the formulation arts as applicant refers to at column 10, lines 1-30. Specifically, Tipton says in column 10, lines 23-26 that when SAIB is used as the HVLCM, ethanol, DMSO, ethyl lactate, ethyl acetate, triacetin, benzyl alcohol, N-methylpyrrolidone, propylene carbonate and glycofurol are preferred, and this list of solvent is not exhaustive. Regarding the oils, Tipton specifically teaches the oils that can be used in formulation that contains HVLCM as noted by applicant to be listed in column 9, lines 42-60, but Tipton in column 10, lines 26-30 lists oils that are not preferred for use with SAIB; further in column 12, lines 18-45 lists oily components with isopropyl myristate, octyl palmitate particularly preferred. Thus, Tipton teaches all the limitations of the claimed composition so that it is proper characterization that the composition of Tipton inherently possesses the properties recited for the composition in claims 2, 4 and 46-50. Therefore, Tipton properly anticipates the com[position in claims 1, 2, 4-6, 10-13, 17, 18, 23-30, 46-50, 54, 55, 57, 70, 71 and 76-78. Please note that claims 54 and 55 limiting the solvent to organic solvent and organic ester inadvertently omitted in the rejections are included and it is brought to applicant's attention that ethyl lactate meets the limitations of claims 54 and 55.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 7, 8, 14-16, 19-22, 41-45, 58-62, 68-71, 73-76 and 79 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Tipton et al. (US 5,747,058) for reasons of record and reiterated herein.

Tipton is described above. Tipton describes compositions that contain CAB and HVLCM and solvents separately (see column 4). Regarding the amounts of HVLCM recited in claims 19-22, in the absence of factual evidence, the claimed amounts are not inventive over the prior art. Regarding the amounts of the drugs, it is noted that Tipton teaches percent amounts of drugs and the specific amounts recited in claims 41-45 is not inventive over the percent amounts taught by Tipton in the absence of factual showing of unexpected results. Furthermore, regarding claims 25 and 16, it is noted that the composition of Tipton is encapsulated and use of soft and hard gelatin capsules are known in the art so that it would be obvious to place the formulation in soft or hard gelatin capsule for delivery. Tipton does not disclose one composition that has HVLCM, CAB, solvent, and rheology modifier. But since Tipton teaches these compositions separately, it would be obvious to combine to combine two compositions to

form a third composition that would be used for the same purpose. [T]he idea of combining them flows logically from their having been individually taught in the prior art. In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Response to Arguments

7. Applicant's arguments filed 3/17/08 have been fully considered but they are not persuasive.

8. The applicant traverses the above rejections in that the specific composition containing HVLCM, solvent, rheology modifier and CAB represent substantial contribution to the art providing optimal sustained delivery of the drug of interest in the stomach environment and not in other environments and that the release of the drug in the stomach provides superior abuse resistant properties under the conditions of drug abuse. The examiner disagrees because it is clear in Tipton that cellulose acetate butyrate (CAB) is formulated with SAIB and active agent to influence the release of the active agent from the composition as shown in Figs. 4, 11, 13, 15 and in Example 6, the solubility of diclofenac decreases with increasing ratio of CAB:SAIB. Therefore, depending on the what the artisan desires regarding the solubility or release of active agent from a composition having SAIB as HVLCM, the artisan would use CAB in the appropriate amounts relative to SAIB that would lead to the desired release pattern/profile. Therefore, Tipton provides suggestion and reasons for including the specific network former, CAB, in a composition comprising solvent, active agent and SAIB. The rejection as it regards to claim 7 and CAB appears to be one of anticipation because Tipton teaches compositions comprising SAIB (HVLCM), ethanol (solvent), drug (diclofenac, flurbiprofen, theophyline) and CAB (network former), specifically keeping in mind that, although applicant elected ethyl lactate

as the solvent, claim 1 is not amended and ethanol meets the limitation of organic solvent. Thus, the compositions identified above in Figs. 2, 11, 13 and 15 and in Example 6 should be capable of the performance of the claimed composition. Therefore, a prima facie case was made in the rejections. The ruling in the KSR case has not been violated by the above rejections.

9. Claims 31, 63, 64 and 72 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Tipton et al. (US 5,747,058) for reasons of record and reiterated herein.

Tipton is described above. One of the drugs in Tipton is codeine, which is an opioid. Tipton does not teach the oxycodone in claims 31, 63, 64 and 72. Since oxycodone and codeine are opioids, and specifically, oxycodone is derived from codeine, it is prima facie obvious that oxycodone can be used in place of codeine and expect to obtain similar relative potency.

Response to Arguments

10. Applicant's arguments filed 3/17/08 have been fully considered but they are not persuasive.

11. Applicant draws attention to the traversal that it would not be obvious to combine specific elements from seven individual lists of materials disclosed by Tipton, that is "the dosage form list, the HVLCM list, the solvent list, the optional element list (including surfactants and oily components), and the polymer lists (biodegradable and non-biodegradable) to wind up with an oral dosage form that has the HVLCM component, a solvent component, a rheology modifier component, and CAB as a network former component." Applicant goes on to say that the use of oxycodone in place of codeine is the 8th in the list that is chosen form the list of biologically active agents and drugs, and since it was not obvious to select 7 items from the lists, it "certainly" would not be obvious to add "yet another list form which to choose a specific

element to add to the combination." Applicant concludes by saying that the Office has not established a prima facie case of obviousness and as such claims 31, 63, 64 and 72 are not rendered obvious by the teachings of Tipton.

12. The examiner disagrees. First of all, the response to applicant's argument traversing the rejection under 35 USC 102 in incorporated here and it clearly shows that Tipton teaches the composition of claim 1 in which the broad composition comprises a drug which a met by any of the drugs listed in Tipton at column 7, lines 60-62 as sedatives and hypnotics of which codeine is one; and any of the drugs in the expanded lists in column 6, line 49 to column 8, line 25 is applicable in the composition of Tipton. Furthermore, it was shown above in response to applicant's traversal of the rejections of claims 7, 8, 14-16, 19-22, 41-45, 58-62, 68-71, 73-76 and 79 that Tipton specifically teaches compositions comprising SAIB (HVLCM), ethanol (solvent), drug (diclofenac, flurbiprofen, theophyline) and CAB (network former), specifically keeping in mind that, although applicant elected ethyl lactate as the solvent, claim 1 is not amended and ethanol meets the limitation of organic solvent as disclosed in Figs. 2, 11, 13 and 15 and in Example 6 of Tipton meeting prima facie case of obviousness. It is further brought to applicant's attention that the list of sedatives and hypnotics includes pentobarbital sodium, phenobarbital, secobarbital sodium, codeine, (a-bromoisovaleryl) urea, carbromal (Tipton at column 7, lines 60-63) and codeine is one out of 6. It is also known that codeine and oxycodone are opioid analgesics as evidenced by claim 4 of US 6,143,322 to Sackler et al. and that oxycodone can be synthesized from codeine as evidenced by claims 1 and 2 of US 6,008,355 to Huang et al. Therefore, one opioid analgesic can be used in place of the other except there is factual evidence that it cannot and the applicant has not provided a factual showing. "When the

PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

No claim is allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

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